

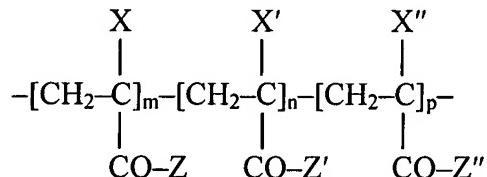
CLAIMS

WHAT IS CLAIMED IS:

1. A coating for an implantable medical device, the coating comprising a first region having a drug incorporated therein, and a second region disposed over the first region, wherein
5 the second region comprises a polymer for modifying the rate of release of the drug, the polymer having in a dry state a glass transition temperature within a range of between about 35°C and about 50°C, wherein the polymer in the dry state contains less than about 1 mass % of water.
2. The coating of Claim 1, wherein the implantable medical device is a stent.
3. The coating of Claim 1, wherein the drug is an anti-inflammatory drug.
- 10 4. The coating of Claim 1, wherein the polymer comprises acrylic polymers, non-acrylic polymers, or blends thereof.
5. The coating of Claim 4, wherein the acrylic polymers are selected from a group consisting of poly(*tert*-butyl acrylate), poly[3-chloro-2,2-*bis*(chloromethyl) propyl acrylate], poly(cyanobenzyl acrylate), poly(2-methoxycarbonylphenyl acrylate), poly(3-
15 methoxycarbonylphenyl acrylate), poly(4-ethoxycarbonylphenyl acrylate), poly(hexadecyl acrylate), poly(3-dimethylaminophenyl acrylate), poly(*p*-tolyl acrylate), poly(*n*-butyl acrylamide), poly(*iso*-decyl acrylamide), poly(octafluoropentyl methacrylate), poly(3,3-dimethylbutyl methacrylate), isotactic poly(methyl methacrylate), poly(*n*-propyl methacrylate), isotactic poly(ethyl chloroacrylate), poly(ethyl fluoromethacrylate), and blends thereof.
- 20 6. The coating of Claim 4, wherein the non-acrylic polymers are selected from a group consisting of, poly(2-cyclohexylethylethylene), atactic poly(*iso*-propylethylene), poly(1,1,2-trimethylethylene), poly(4,4 dimethylpentylethylene), poly(2,2,2-trifluoroethoxytrifluoroethylene), poly(4-methoxybenzoylethylene), poly(3,4-

dimethoxybenzoylethylene), poly(vinyl fluoride), poly(cyclopentanoyloxyethylene), 60% syndiotactic poly(formyloxyethylene), poly[4-(*sec*-butoxymethyl) styrene], poly(4-butoxystyrene), and blends thereof.

7. The coating of Claim 4, wherein the acrylic polymers have formula



wherein:

X, X', and X" is each, independently, a hydrogen atom or an alkyl group, such as methyl group;

Z, Z', and Z" is each, independently, a substituted or unsubstituted amino group or an

15 alkoxy group OR, OR', and OR", where R, R' and R" is each, independently, a C₁ to C₁₂ straight chained or branched aliphatic radical; and

"m," "n," and "p" is each an integer, where m > 0, n ≥ 0, and p ≥ 0.

8. The coating of Claim 1, wherein the polymer has the melting temperature above about 50°C, and additionally including a substance having the melting temperature within the 20 range between about 32 °C and 40°C.

9. A coating for an implantable medical device, comprising a polymer and a drug incorporated therein, wherein a glass transition temperature of the polymer is the temperature that allows the morphology of the polymer to change the release rate of the drug when a body temperature of the patient in which the device has been implanted rises to a temperature above 25 the patient's normal body temperature.

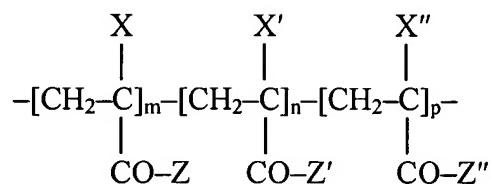
10. The coating of Claim 9, wherein the implantable medical device is a stent.

11. The coating of Claim 9, wherein the glass transition temperature of the polymer in a dry state is about 37°C, wherein the polymer in the dry state contains less than about 1 mass % of water.

5 12. The coating of Claim 9, wherein the polymer comprises acrylic polymers, non-acrylic polymers, or blends thereof.

13. The coating of Claim 12, wherein the acrylic polymers are selected from a group consisting of poly(*tert*-butyl acrylate), poly[3-chloro-2,2-*bis*(chloromethyl) propyl acrylate], poly(cyanobenzyl acrylate), poly(2-methoxycarbonylphenyl acrylate), poly(3-methoxycarbonylphenyl acrylate), poly(4-ethoxycarbonylphenyl acrylate), poly(hexadecyl acrylate), poly(3-dimethylaminophenyl acrylate), poly(*p*-tolyl acrylate), poly(*n*-butyl acrylamide), poly(*iso*-decyl acrylamide), poly(octafluoropentyl methacrylate), poly(3,3-dimethylbutyl methacrylate), isotactic poly(methyl methacrylate), poly(*n*-propyl methacrylate), isotactic poly(ethyl chloroacrylate), poly(ethyl fluoromethacrylate), and blends thereof.

15 14. The coating of Claim 12, wherein the acrylic polymers have a formula



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wherein:

X, X', and X'' is each, independently, a hydrogen atom or an alkyl group, such as methyl group;

Z, Z', and Z" is each, independently, a substituted or unsubstituted amino group or an alkoxy group OR, OR', and OR", where R, R' and R" is each, independently, a C₁ to C₁₂ straight chained or branched aliphatic radical; and

"m," "n," and "p" is each an integer, where m > 0, n ≥ 0, and p ≥ 0.

5 15. The coating of Claim 12, wherein the non-acrylic polymers are selected from a group consisting of, poly(2-cyclohexylethylethylene), atactic poly(*iso*-propylethylene), poly(1,1,2-trimethylethylene), poly(4,4 dimethylpentylethylene), poly(2,2,2-trifluoroethoxytrifluoroethylene), poly(4-methoxybenzoylethylene), poly(3,4-dimethoxybenzoylethylene), poly(vinyl fluoride), poly(cyclopentanoyloxyethylene), 60% syndiotactic poly(formyloxyethylene), poly[4-(*sec*-butoxymethyl) styrene], poly(4-butoxystyrene), and blends thereof.

10 16. The coating of Claim 9, wherein the drug is an anti-inflammatory drug.

15 17. A method of coating an implantable medical device, comprising depositing a first layer on the device, the first layer including a drug incorporated therein, and depositing a second layer over the first layer, the second layer comprising a polymer for modifying the rate of release of the drug, wherein the polymer has a glass transition temperature in a dry state within a range of between about 35°C and about 50°C, wherein the polymer in the dry state contains less than about 1 mass % of water.

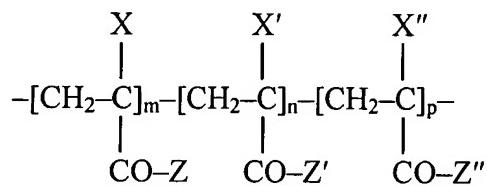
20 18. The method of Claim 17, wherein the implantable medical device is a stent.

20 19. The method of Claim 17, wherein the therapeutic agent is an anti-inflammatory drug.

20 20. The method of Claim 17, wherein the polymer comprises acrylic polymers, non-acrylic polymers, or blends thereof.

21. The method of Claim 20, wherein the acrylic polymers are selected from a group consisting of poly(*tert*-butyl acrylate), poly[3-chloro-2,2-*bis*(chloromethyl) propyl acrylate], poly(cyanobenzyl acrylate), poly(2-methoxycarbonylphenyl acrylate), poly(3-methoxycarbonylphenyl acrylate), poly(4-ethoxycarbonylphenyl acrylate), poly(hexadecyl acrylate), poly(3-dimethylaminophenyl acrylate), poly(*p*-tolyl acrylate), poly(*n*-butyl acrylamide), poly(*iso*-decyl acrylamide), poly(octafluoropentyl methacrylate), poly(3,3-dimethylbutyl methacrylate), isotactic poly(methyl methacrylate), poly(*n*-propyl methacrylate), isotactic poly(ethyl chloroacrylate), poly(ethyl fluoromethacrylate), and blends thereof.

22. The method of Claim 20, wherein the acrylic polymers have formula



wherein:

X, X', and X'' is each, independently, a hydrogen atom or an alkyl group, such as methyl group;

Z, Z', and Z" is each, independently, a substituted or unsubstituted amino group or an alkoxy group OR, OR', and OR", where R, R' and R" is each, independently, a C₁ to C₁₂ straight chained or branched aliphatic radical; and

"m," "n," and "p" is each an integer, where $m > 0$, $n \geq 0$, and $p \geq 0$.

23. The method of Claim 20, wherein the non-acrylic polymers are selected from a group
consisting of, poly(2-cyclohexylethylethylene), atactic poly(*iso*-propylethylene), poly(1,1,2-
25 trimethylethylene), poly(4,4 dimethylpentylethylene), poly(2,2,2-

trifluoroethoxytrifluoroethylene), poly(4-methoxybenzoylethylene), poly(3,4-dimethoxybenzoylethylene), poly(vinyl fluoride), poly(cyclopentanoyloxyethylene), 60% syndiotactic poly(formyloxyethylene), poly[4-(*sec*-butoxymethyl) styrene], poly(4-butoxystyrene), and blends thereof.

5 24. The method of Claim 17, wherein the polymer has the melting temperature above about 50°C, and additionally including a substance having the melting temperature within the range between about 32 °C and 40°C.